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Device name
Trade Name : Periform
Common Name : Perineometric Probe
Classification : Perineometer (per 21 CFR section 884.1425)

Identification of Predicate Device
As the purpose of this 510k submission is solely to endorse a change in probe body material the predicate device is identified as the currently marketed Periform 510k Number 981277

Description of Device
The Periform is a vaginal perineometric probe designed specifically for the acquisition of the naturally present superficial EMG signals of the human vaginal wall. Surface electromyography (sEMG) is the technique of measuring and filtering the electrical impulse (action potential) signals generated by muscle fibres during contraction.

The probe conducts these signals to a biofeedback device for further processing. The anatomy of the pelvic floor presents a difficulty in obtaining these signals. The use of a perineometric probe overcomes this difficulty.

The purpose of the Periform is to improve the voluntary control and strength of the pelvic floor muscles with the aid of biofeedback equipment.

Intended Uses

Indications
1.Treatment of Stress, Urge and Mixed Incontinence.
2.Sensor for SEMG behavioural training.
3.Facilitation in identification of pubococcygeus muscles.
4.Strengthening of the pelvic floor muscles through biofeedback assisted pelvic floor exercises.
5.Qualitative evaluation of the pelvic floor musculature using the 'Pelvic Floor Contraction Indicator'

Contraindications/ DO NOT USE
1.Do not use during the menstrual period or when pregnant
2.Do not use if symptoms of bladder infection are present
3.Do not use if symptoms of a vaginal infection are present
4.Do not use if patient has a history of urinary retention or symptoms thereof
5.Do not use with patients who cannot handle the device properly
6.Do not use while pregnant or while attempting to become pregnant

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7.Do not use if patient has an anatomical vaginal morphology and /or structure that does not permit proper insertion of the probe
8.Do not use this device in conjunction with electrical muscle stimulation
9.Do not use if patient is unable or unwilling to use device as directed and indicated.

Device Comparison

	Modified Device	Predicate device
	Periform Perineometric Probe	Periform Perineometric Probe
510(k) Number		K981277
Mode of Use	Reusable for single patient	Same
Parameter monitored	Aggregate surface electromyogram	Same
User feedback	None	Same
Intended Use	To produce biofeedback signals for processing by an external feedback device	Same
Indications for use	Treatment of stress and urge incontinence and facilitation of pelvic floor exercises	Same
Performance standards	Currently no performance standards exist for sEMG biofeedback perineometric devices	Same
Target population	Adult female urinary incontinence patients	Same
Anatomical Sites designed for use	Female Pubococcygeus muscle area	Same
Energy used and / or delivered	No energy used or delivered only transported	Same
Compatibility with environment and other devices	Probe is not known to conflict with other devices or cause environmental hazards	Same
Where used	Hospitals, Clinics, Doctors offices or home use under Clinician's supervision	Same
Sterility	Probe does not need to be sterile. Appropriate cleaning procedure included in instructions for use.	Same
# of electrode contacts	2	Same
# of leadwires	2	Same
Transducers	None	Same
Body materials	BP Empera Impact Polystyrene Type 514	Huntsman Chemical High Impact Polystyrene, Type 564
Masterbatch colouring used in body material	None	Same
Biocompatibility of body material	Biocompatible	Same
Pelvic Floor contraction indicator included ?	Yes	Same

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Pelvic Floor contraction indicator (PFCI) Tip & Base material	ATO RMNCD natural Nylon 6 Hampton white masterbatch HCM10P at 3% mix	Huntsman Chemical High Impact Polystyrene, Type 564
PFCI shaft material	Stamylan low density polythene grade 2100 TNOO	Same
Electrode material	Medical Grade Stainless Steel Type 316S31	Same
Biocompatibility of Electrode Material	Biocompatible	Same
Electrode orientation	Longitudinal	Same
Construction	Two mouldings enclosing two electrodes, ultrasonically welded together	Same
Sensing method	sEMG biofeedback recording	Same
Feedback Modes	No direct feedback to user	Same
Electrical safety	Device is passive : not electrically powered	Same
Electrode and conductive media	Not applicable	Same
Intentional electric currents	Warning included in Instructions for use. Socket type prevents *easy* intentional connection to AC source	Same
Unintentional electric currents	Probe is to be used with appropriate biofeedback device as stated in Basic Design Description, or with PFCI only	Same
Risk of mechanical injury	Risk prevention considered in design process	Same
Chemical safety	Body and electrodes constructed of chemically inert materials	Same
Shaft length	76mm	Same
Width across electrodes	34mm	Same
Maximum flange dimension	28.2mm	Same
Spacing type	Axial, incremental	Same
Electrode surface area	4.9cm^2 x 2	Same

Non Clinical Performance Data

An impedance test was performed to demonstrate that the Periform is capable of transporting electrical signals with minimum attenuation. Various frequencies were used in order to verify that the Periform would be effective in the range of frequencies encountered in pelvic floor biofeedback (typically less that 200Hz). The test shows that the Periform exhibits the low impedance values needed to accurately record pelvic floor muscle activity.

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Bio-compatibility testing

The materials used in the Periform have undergone safety tests which prove their safety with respect to the required standard for each test.

Material	Test performed	Results
Probe body Polystyrene BP Empera 514	Cytotoxicity ISO10993-5 Meets requirements of 21CFR177.1640 polystyrenes	Non toxic Not classified as irritant or Skin sensitizer
Probe electrode Medical Grade Stainless steel 31S316	Standard medical grade stainless steel for use in medical devices for transient contact (<2hours)	Non toxic
Indicator tube Polythene Stamylan LDPE Grade 2100 TNOO **Indicator tip & base** Nylon ATO RMNCD Natural nylon 6	No test performed as these components do not intentionally come into contact with the body	Not applicable

Conclusion

The change in material for the probe body has been approved in the EU under the Medical Devices Directive 93/42/EEC since 22 March 2000 and preceding this report between 11 and 12 thousand Periforms have been marketed in the European Union with no recorded customer complaint, customer return, incident or adverse incident (Neen Healthcare runs an accredited and externally audited ISO9001 [EN46001] quality system) relating to the materials change.

The new material provides enhanced physical characteristics with superior manufacturing properties which will reduce failure rates and improve quality.

The Periform is safe and effective for it's intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Mr. Mark Read
Technical Services Manager
NEEN HealthCare
Old Pharmacy Yard
Church Street, Dereham
Norfolk, NR19 1DJ
ENGLAND

Re: K002617
Periform Perineometric Probe, Model 8300
Dated: February 12, 2001
Received: February 12, 2001
Regulatory Class: II
21 CFR §884.1425/Procode: 85 HIR

Dear Mr. Read:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K002617

PREMARKET NOTIFICATION

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Neen Healthcare

510(k) Number (if known): awaiting premarket notification approval

Device Name: Periform

Indications For Use:

1. Treatment of Stress, Urge and Mixed Incontinence.
2. Sensor for SEMG behavioural training.
3. Facilitation in identification of pubococcygenus muscles.
4. Strengthening of the pelvic floor muscles through biofeedback assisted pelvic floor exercises.
5. Qualitative evaluation of the pelvic floor musculature using the 'Pelvic Floor Contraction Indicator'

Target population :

Adult female urinary incontinence patients.

Anatomical sites :

Female Pubococcygeus muscle area.

David C. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiolo...
510(k) Numbe... K002617

Prescription Use ✓
(Per 21 CFR 801.109)